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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,106	01/27/2004	Danny Lewis	PRJ-006CN	2190

959 7590 09/27/2005  
LAHIVE & COCKFIELD, LLP.  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER
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AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/766,106

Applicant(s)

LEWIS ET AL.

Examiner

Carlos A. Azpuru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Receipt is acknowledged of the amendment, extension of time, and terminal disclaimer filed 07/11/2005.

The rejection under the judicially created doctrine of obviousness-type double patenting over US. Patent No. 6,706, 829 is hereby withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 21 is unclear in the use of the phrase "predominantly a single species". Clarification is requested as it the terms seem to indicate that multiple forms of this pharmaceutical may be formed. As understood by this examiner, the claimed pharmaceutical is the combination of a pegylated interferon (or any conjugate of a hydrophilic polymer and interferon) and a biodegradable polymer. The formation of

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'species' of this product is not something applicant has described in the specification. While it is understood that the term " species" itself is art recognized, the term itself is never described in terms in which the ordinary practitioner would have been able to make and or use the invention as described. Applicant is requested to clarify this terminology.

Claim 1 contains the phrase "predominantly a single site on the interferon" which is not found in the original specification. This terminology is considered new matter.

Correction is requested.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Lam et al (Controlled Release Society 29<sup>th</sup> Annual Meeting).

Lam et al disclose a controlled release formulation comprising a biodegradable polymer in combination with a conjugate of pegylated monoclonal antibody fragments in the form of microspheres of poly(lactic-co-glycolic) acid (see Abstract). The instant claim is anticipated by Lam et al.

Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al (Biomaterials 23 (2002) 2311-2317).

Kim al disclose a controlled release formulation comprising a biodegradable polymer in combination with a conjugate of pegylated epidermal growth factor in the form of microspheres of poly(lactic-co-glycolic) acid (See Abstract). The instant claim is anticipated by Kim et al.

Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al (Proceed Int'l Symp. Control. Rel. Bioact. Mater., 28(2001), Controlled Release Society).

Kim al disclose a controlled release formulation comprising a biodegradable polymer in combination with a conjugate of pegylated peptides such as insulin in the form of microspheres of poly(lactic-co-glycolic) acid (See Abstract). The instant claim is anticipated by Kim et al.

Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Diwan et al (International Journal of Pharmaceutics 252 (2003) 111-122).

Diwan et al disclose pegylation of alpha- interferon in combination with poly(D,L-lactide-co-glycolide) (see Abstract). The formulation of the composition is an intended

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use. The microspheres of the pegylated interferon are prepared by dissolving PLGA copolymer and the pegylated conjugate to form a solution. Formation of microspheres follows (see page 113, 2.5). The instant claims are anticipated by Diwan et al.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Proceed Int'l Symp. Control. Rel. Bioact. Mater., 28(2001), Controlled Release Society).

As set out above, Kim et al disclose a controlled release formulation comprising a biodegradable polymer in combination with a conjugate of pegylated peptides such as insulin in the form of microspheres of poly(lactic-co-glycolic) acid (See Abstract). While Kim et al do not set out biphalin, leu-enkephalin, or somatostatin, the teaching of the paper is generic to all peptides. Those of ordinary skill would therefore have expected similar controlled release therapeutic results from the conjugation of any peptide in

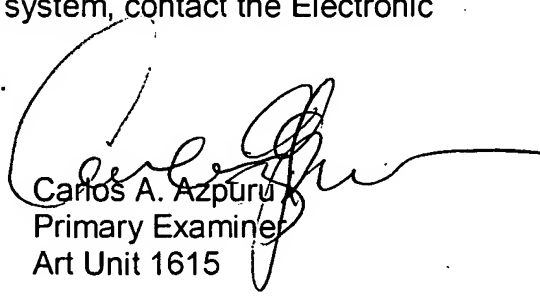
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combination with a hydrophilic polymer as taught by Kim et al. The instant claim would have been obvious in view of Kim et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Carlos A. Azpuru  
Primary Examiner  
Art Unit 1615

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